

Complications of cardiac catheterization: one centre's experience

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Data on complication rates in a cardiac catheterization laboratory were prospectively gathered over a 6-year period. During this time 7960 catheterizations were performed. Death occurred in seven (0.1%) of the cases. The difference between the mortality rates for procedures performed with and without systemically administered heparin (0.04% and 0.2% respectively) was barely statistically significant ($p < 0.05$). A significant complication occurred in 1.5% of the cases; however, most did not have long-term sequelae. No significant change in the annual rate of such complications was seen during the study period. Such a tabulation permits audit of quality of care, points out changing trends in morbidity and offers meaningful information on the safety of cardiac catheterization to referring physicians and their patients.

Enquête prospective sur la survenue des complications dans un laboratoire de cathétérisme cardiaque. En 6 ans on a fait 7960 cathétérismes, avec sept décès (0,1%). Il existe une différence à peine statistiquement significative ($p < 0,05$) entre les taux de mortalité reliés aux examens faits avec et sans héparinothérapie (soit 0,04% et 0,2% respectivement). Les complications importantes surviennent dans 1,5% des cas, mais la plupart d'entre elles ne comportent pas de séquelles durables; leur fréquence annuelle ne fluctue pas de façon significative. Ce genre d'enquête permet de surveiller la qualité du travail, de montrer l'évolution dans le temps de la fréquence relative des complications et de renseigner le médecin, et les malades qu'il adresse, sur la sécurité du cathétérisme cardiaque.

Medical procedures, whether diagnostic or therapeutic, invariably include both a chance of benefit and a chance of harm to the patient. The acceptable ratio of one to the other will vary, depending on the value of the procedure and the seriousness of the disease. However, it is important to know each of these aspects of the procedures we use.

Cardiac catheterization has been performed routinely for more than 20 years. Its increasing application over the years reflects its accepted value in everyday diagno-

sis and decision-making in cardiology. However, physicians who refer patients for cardiac assessment (including catheterization) should be aware of contemporary complication rates of the procedure, the better to balance the chance of harm against the anticipated benefit for their patients.

A number of surveys of complications of cardiac catheterization have been made over the past 15 years.¹⁻⁶ Generally these have been retrospective studies; doubt must always exist as to whether all patients and all complications have been recorded in such studies. We report a prospective tabulation of all the procedures performed and complications thereof over a 6-year period at the University of Ottawa Heart Institute. The main reason for this tabulation has been to audit the quality of medical care, but it is hoped that the data may be of more general value as well.

Methods

Our current cardiac catheterization suite (two laboratories) opened in June 1976. Prior to this a method of recording all procedures and complications was decided on and has since been in effect. A procedure is counted once a cardiac catheter or guidewire has passed the skin. At the end of each procedure a three-copy form (Fig. 1)

CARDIAC UNIT OTTAWA CIVIC HOSPITAL CARDIAC CATHETERIZATION RECORD							
OHIP NO	SEX	DATE OF BIRTH	RELATION OF PATIENT TO SUBSCRIBER	HT	WT	BSA	
PATIENTS FULL ADDRESS							
DATE	B P PRIOR TO CATH			PULSES POST. TIB. DORS. PED. RADIAL		RIGHT	LEFT
PREMEDICATION							
CARDIOLOGIST				ASSISTANT			
SCRUB NURSE				CIRCULATING NURSE			
DRUGS ADMINISTERED				REMARKS			
B P FOLLOWING CATH				PULSES POST. TIB. DORS. PED. RADIAL		RIGHT	LEFT
RIGHT HEART STUDY <input type="checkbox"/>		FEMORAL <input type="checkbox"/>		BRACHIAL <input type="checkbox"/>			
RETROGRADE AORTIC STUDY <input type="checkbox"/>		FEMORAL <input type="checkbox"/>		BRACHIAL <input type="checkbox"/>			
TRANSEPTAL LEFT HEART STUDY <input type="checkbox"/>		HIS BUNDLE STUDY <input type="checkbox"/>		ENDOMYOCARDIAL BIOPSY <input type="checkbox"/>			
PACEMAKER <input type="checkbox"/>		AORTIC ROOT <input type="checkbox"/>		ATRIAL PACING <input type="checkbox"/>			
ANGIOGRAPHY: LEFT VENTRICLE <input type="checkbox"/>		SELECTIVE CORONARIES <input type="checkbox"/>		BYPASS GRAFTS <input type="checkbox"/>			
OTHER STUDIES		OTHER <input type="checkbox"/>					
COMPLICATIONS (WITHIN 24 HOURS OF STUDY)							
<input type="checkbox"/> NONE <input type="checkbox"/> ASYSTOLE <input type="checkbox"/> VENTRICULAR FIBRILLATION <input type="checkbox"/> OTHER ARRHYTHMIA <input type="checkbox"/> INTRAMYOCARDIAL INJECTION <input type="checkbox"/> CARDIAC/VASCULAR PERFORATION <input type="checkbox"/> HYPOTENSION <input type="checkbox"/> HEMATOMA <input type="checkbox"/> OTHER				<input type="checkbox"/> ALLERGIC REACTION <input type="checkbox"/> ARTERIAL THROMBOSIS <input type="checkbox"/> VENOUS THROMBOSIS <input type="checkbox"/> MYOCARDIAL INFARCTION <input type="checkbox"/> STROKE <input type="checkbox"/> OTHER EMBOLIC COMPLICATION <input type="checkbox"/> DEATH			
REMARKS							
CCL 2 (Rev 3/79)							
SIGNATURE							

Fig. 1—Form completed by staff cardiologist at end of each cardiac catheterization performed at University of Ottawa Heart Institute.

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is completed by the staff cardiologist; our nursing staff is assiduous in not allowing the cardiologist or patient to leave the suite until the form has been filled out. One copy of the form becomes part of the hospital's patient record.

For the tabulation we consider as a significant complication any of the morbid events in Table I that may occur during the procedure or in the subsequent 24 hours. The only exceptions are complications clearly attributable to cardiac surgery performed during that time. We also tabulate minor complications, such as urticaria, supraventricular dysrhythmias and lesser-size hematomas, but they are not considered further in this report. Cardiologists are expected to report significant complications that occur in the 24 hours following the procedure. In addition, the physically compact nature of the institute and the constancy of the nursing staff give the director of the laboratories full access to this information. The procedures and complications are reviewed quarterly, with correction of the data if necessary, at a medical audit meeting of the physicians involved in catheterization.

For the purposes of this report the data from the first 6 full years of operation of the suite (1977–82) have been included. Complications specifically related to coronary angioplasty in the last 3 years have been excluded.

Results

During the 6 years a total of 7960 catheterization procedures were performed by six cardiologists. Catheterization of the left side of the heart was carried out in 7552 cases (95%) and of the right side of the heart in 1422 cases (18%); in most cases the latter was combined with the former, but occasionally right-heart catheterization alone was performed (e.g., for pulmonary angiography). Of the left-sided procedures 7369 (98%) were done percutaneously from the leg and only 183 (2%) by brachial cutdown, which reflects the preference in our laboratory. Selective coronary angiography was carried out in 7130 cases (90%) and was the single most common diagnostic procedure. The absolute number of procedures performed gradually increased, from 1012 in 1977 to 1730 in 1982 (Table II).

Obviously the most important possible complication of cardiac catheterization is death, and, conversely, the mortality rate is the standard of safety by which laboratories are judged. In our series death due to catheterization occurred in seven cases (0.1% of the procedures); we excluded only cases in which the patient was truly moribund on entry to the laboratory or died before the procedure could be started. Of the seven deaths one occurred in a patient with critical aortic stenosis who collapsed following aortic root angiography, and one was related to hypovolemic shock from retroperitoneal hemorrhage following perforation of the iliac artery. The other five deaths were all related to the performance of selective coronary angiography. In one case the patient suffered infarction of the anterior wall following injection of the left coronary artery; he died 3 days later in congestive heart failure, and consent for autopsy was not obtained. The other four patients died

of electromechanical dissociation, with abrupt pump failure, during coronary angiography. They could not be resuscitated despite balloon counterpulsation and, in two, aortocoronary bypass surgery. An autopsy was performed in all four cases; acute coronary occlusion was demonstrated in two (one by a fresh thrombus and one by dissection of an atheromatous plaque in situ). In the other two cases no acute pathoanatomic change in the coronary arteries was demonstrated.

There were several clinical and radiographic features common to all five patients who died in relation to coronary angiography: a history of previous infarction; severe, often rest, angina; poor contraction of the left ventricle; and greater than 50% stenosis of the left main-stem artery and of three major coronary arteries.

Other major but nonfatal ischemic complications included myocardial infarction and stroke. Transmural myocardial infarction, recognized by QRS changes on an electrocardiogram and a transient rise of serum enzyme levels, occurred in eight (0.1%) of the patients undergoing a coronary angiographic procedure. It occurred after the procedure (by as much as 20 hours) as often as it did during it, which suggests a multifactorial cause. In many more cases prolonged ischemic chest pain occurred during or after the procedure but without evidence of myocardial necrosis. Myocardial infarction never occurred in the 12.6% of the patients whose coronary angiograms were normal.

Stroke denoted a spectrum of events ranging from transient focal cerebral ischemia lasting for several hours to persistent frank hemiplegia. Overall, it occurred in nine (0.1%) of the left-sided cardiac catheterizations.

Table I—Significant complications of cardiac catheterization

Death
Myocardial infarction
Stroke
Cardiac perforation
Major hematoma
Vascular injury (e.g., thrombosis, false aneurysm)
Anaphylactoid shock
Pulmonary edema
Ventricular tachycardia
Ventricular fibrillation
Complete heart block
Asystole

Table II—Number of cardiac catheterizations performed at the University of Ottawa Heart Institute during 1977–82 and relative rate of significant complications

Year	No. of procedures performed	Complication rate (%)
1977	1012	1.5
1978	1201	2.0
1979	1198	1.9
1980	1303	1.5
1981	1516	1.5
1982	1730	1.5

Other serious but rare complications included pulmonary edema (four cases), anaphylactoid shock (three), acute renal failure (two) and perforation of the heart (two), each occurring in less than 0.05% of all the cases. None was fatal.

More common significant complications were transient rhythm disorders and injury to the catheterized vessel. Ventricular fibrillation (38 cases) and tachycardia (10) were the commonest significant abnormal rhythms, occurring overall in 48 cases (0.6%). These complications were usually related to selective coronary or bypass graft injection or to the passage of a catheter across the outflow portion of the right or left ventricle. In most of the cases of tachycardia and in all the cases of fibrillation, precordial shock was required to restore the normal rhythm. These patients routinely were monitored after the procedure was completed, but if ventricular ectopy had not been clinically evident before the procedure it posed no problem afterward. In 16 cases (0.2%) bradycardia, in the form of complete heart block (5) or asystole (11) requiring a chest thump, occurred. Complete heart block was treated by temporary cardiac pacing, and only in this group of patients was hospital discharge delayed.

Vascular injury, when it occurred, was a cause of significant morbidity and prolongation of hospital stay. Arterial injury (including thrombosis [17 cases], major hematoma or vessel laceration [6], false aneurysm [6], thromboembolism [5] and arteriovenous fistula [1]) occurred in 35 (0.5%) of the left-sided catheterizations. All the patients were promptly treated by surgical repair; there was minimal long-term morbidity. The incidence of arterial injury in transfemoral procedures was 0.4% and in transbrachial procedures 2.7%. Thrombosis of a catheterized vein in the arm or leg occurred in three (0.2%) of the right-sided catheterizations, relatively as often as arterial thrombosis. It usually became evident only after the patient had been discharged, and thus the true incidence may have been higher than was recognized. Treatment included hospital admission, bed rest and therapy with anticoagulants.

The relative annual rate of significant complications did not change significantly over the 6 years (Table II).

Of the transfemoral catheterizations of the left side of

the heart 4992 were performed by four cardiologists with systemic administration of 3000 to 5000 U of heparin; the other 2560 were performed by two cardiologists without the use of heparin. In the former group there were two deaths and in the latter, five; the difference between the rates (0.04% and 0.2% respectively) was barely statistically significant ($p < 0.05$). On the other hand, significant differences between the two groups did not exist in the relative rates of nonfatal myocardial infarction, stroke major hematoma or femoral artery thrombosis (Table III).

Discussion

Since cardiac catheterization has become a routine procedure in larger urban centres, the physicians involved have demonstrated an interest in monitoring the safety of the procedure. However, reporting or even keeping data on complications has not been a universal requirement. Thus, data that do exist usually evolve from surveys of major hospitals in which the more interested participate. Such data may have limited application to hospitals not surveyed or not responding. Nevertheless, data from the best laboratories have provided standards on which other groups may set their sights.

Undoubtedly complication rates have fallen in the past 15 years, for various reasons. A survey done in 1970-71 of 47 000 catheterizations revealed a mortality rate of 0.13% for the transbrachial technique and 0.78% for the transfemoral technique.² The latter figure broke down to 0.16% for laboratories performing more than 400 procedures per year and 1.3% for those performing fewer than 100 per year. In other studies the mortality rate reported for transfemoral coronary arteriography has been as high as 2.4%.⁷ Judkins and Gander,⁸ however, pointed out that the transfemoral technique could be as safe as the transbrachial technique if the angiographer was competent and well trained, and if the thrombogenicity of catheters and guidewires was compensated for with systemic administration of heparin (as is essentially the case in transbrachial catheterization). They advised that each laboratory use, for the most part, one or the other of the two techniques so as to become expert with it. They also suggested that laboratories with a mortality rate greater than 0.1% reassess their methods and that those with a rate greater than 0.3% stop doing coronary angiography until the problems were corrected.

By 1975 it was apparent that complication rates for the transfemoral technique were declining. A survey of almost 90 000 cases demonstrated a mortality rate of 0.16% for this technique, which was not significantly different from that for the transbrachial technique (0.10%).³ This lack of difference was confirmed by a more recent report from the Coronary Artery Surgery Study, in which the overall mortality rate following catheterization was 0.2%; in large laboratories the mortality rates for the two techniques were similar.⁴ A recent and larger survey also showed an overall mortality rate of 0.10% for both techniques.⁶

There is not general agreement as to why complication rates for transfemoral catheterization have fallen.

Table III—Number of occurrences of five significant complications in two groups receiving or not receiving heparin during catheterization of left side of heart

Complication	No. (and %) of occurrences in group	
	Receiving heparin (n = 4992)	Not receiving heparin (n = 2560)
Death	2 (0.04)*	5 (0.2)*
Myocardial infarction	5 (0.1)	3 (0.12)
Stroke	5 (0.1)	4 (0.16)
Major hematoma	4 (0.08)	2 (0.08)
Femoral artery thrombosis	8 (0.16)	4 (0.16)

*The difference between these two rates was significant at $p < 0.05$.

Greater skill and experience of those performing the procedure, shorter procedure times, and improved catheter and contrast materials seem likely factors. As Bourassa and Noble⁹ have pointed out, the lower rates must be viewed in the perspective of the changing spectrum of patients being studied: patients undergoing the procedure today are sicker than those in the past, and this tends to increase rates of complication. In our experience, as in that of Bourassa and Noble, complication rates did not fall when 1000 procedures or more per year were performed.

Systemic administration of heparin has been advocated by some as reducing the risk of thromboembolism from the guidewire, catheter or site of entry in the vessel.^{10,11} Others have found that the rate of complications following transfemoral catheterization without administration of heparin is no different from that with administration of heparin.^{4,6} We found the mortality rate to be barely significantly lower when heparin had been given but would be cautious in drawing the conclusion that other factors, such as experience and technique, were not equally involved. Indeed, an analysis of nonfatal ischemic or hemorrhagic events in our series showed no difference in the rates of these events with or without administration of heparin. However, because of the theoretical possibility of thrombus formation we have adopted the policy of giving 3000 U of heparin whenever transfemoral catheterization of the left side of the heart is done.

Though our rate of significant complications (1.5%) is still far from ideal, it agrees well with that found in a recent prospective survey of more than 53 000 patients in 66 well regarded laboratories (1.8%).⁵ Moreover, not all morbid events recorded in the 24 hours following catheterization are likely due to the procedure itself (though in practice this may be impossible to discern). Coronary disease is at times dramatic and unpredictable; in patients awaiting a postponed procedure the incidence of similar events occurring spontaneously is almost as high as the incidence after catheterization.^{12,13} Furthermore, not all complications are of equal significance to the patient. Unexpected ventricular fibrillation, though a most unpleasant experience for the patient, has virtually no long-term sequelae (other than an aversion to catheterization). Vascular injury is usually quickly detected and repaired, long-term disability being uncommon. Thus, death, myocardial infarction and stroke (which occurred in 0.3% of our cases) are the hazards that one must seriously consider and discuss with the patient. In our experience and that of others, death occurs largely in patients with severe, especially coronary, heart disease.^{6,10,14} Both death and myocardial infarction are particularly unlikely in patients who do not have structural heart disease.

There are a number of benefits of an ongoing tabulation of mortality and morbidity associated with cardiac catheterization. First, it allows the laboratory to compare its performance with that of others. Clearly the value of such data would be greatly enhanced if a national registry of cardiac procedures and complications were kept. Second, the laboratory can use these data to identify disturbing trends that call for a reassessment of techniques or, conversely, to set isolated

instances in proper perspective. Third, it allows referring physicians to weigh the relative risks and benefits for their patients. Last, it allows physicians performing catheterization to advise their patients as to the true risks of complication in their own laboratory, a practice endorsed by medicolegal authorities.

In summary, we found the risk of complications in our laboratory to be stable and acceptably low. Cardiac catheterization in similar laboratories is a relatively safe procedure that should be used whenever the knowledge to be gained by it will be of substantial benefit to the patient or the physician.

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